CHILDRENS SILFEDRINE - pseudoephedrine hydrochloride liquid Silarx Pharmaceuticals, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Children's Silfedrine Liquid

Active Ingredient: Pseudoephedrine hydrochloride 15 mg (in each 5 mL(teaspoonful)(TSP))

Purpose: Nasal decongestant

Uses temporarily relieves nasal congestion due to

- common cold
- hay fever
- other upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- promotes nasal and/or sinus drainage

Warnings

DO NOT USE IN CHILDREN UNDER 4 YEARS OF AGE

• **Do not use** if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart diseases
- high blood pressure
- thyroid disease
- diabetes

When using this product do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do not improve within 7 days or accompanied by fever

Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away (1800-222-1222).

Directions

- Do not exceed 4 doses in 24 hours.
- Repeat dose every 4 hours if needed.

Children under 4 years of age	DO NOT USE	
Children 4 to 5 years of age	1 teaspoonful(TSP)	
Children 6 to 11 years of age	2 teaspoonfuls (TSP)	

Other information

Inactive ingredients

citric acid, FD&C blue no. 1, FD&C red no. 40, glycerin, grape flavor, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution.

Questions

888-974-5279

Manufactured by:

Silarx Pharmaceuticals, Inc 1033 Stoneleigh Ave Carmel, NY 10512 USA

NDC 54838-104-40

Children's

Silfedrine Liquid

Pseudoephedrine Hydrochloride

Nasal Decongestant

- Non-drowsy Formula
- GRAPE FLAVOR
- Alcohol/Sugar Free

DO NOT USE IN CHILDREN **UNDER 4 YEARS OF AGE**

DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING

118 mL (4 fl oz)

ctive ingredient (in each 5 mL (teaspoonful) (TSP)) Purpose

temporarily relieves nasal congestion due to a common cold hay fever

common cold

2 anp

relieves

promotes nasal and/or sinus drainage

hay fever a other upper respiratory allergies a temporarily sngestion and pressure a promotes nasal and/or sinus draina

temporarily relieves nasal

Active Ingredient (in each 5 mL (teaspoonful) (TSP))

Drug

■ DO NOT USE IN CHILDREN UNDER 4 YEARS OF AGE ■ Do not use other upper respiratory allergies
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■ high blood

Stop use and ask a doctor if a nervousness, dizziness or sleeplessness symptoms do not improve within 7 days or are accompanied by tever Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). pressure # thyroid disease # diabetes
When using this product do not use more than directed

Keep out of the reach of children, in case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Repeat dose every 4 hours if needed.

Directions - Do not exceed 4 doses in 24 hours.

Stop use and ask a doctor if a nervousness, dizziness or siegliessness occur a symptoms do not improve within 7 days or are

accompanied by fever

When using this product do not use more than directed

ressure - fryroid disease - diabetes

 Do not exceed 4 doses in 24 hours. Children 6 to under 11 years of age Children 4 to 5 years of age Directions

> 2 teaspoonfuls (TSP 1 teaspoonful (TSP

> > Children 6 to under 11 years of age

Children 4 to 5 years of age

4 years of age

Idren under

DO NOT USE

2 teaspoonfuls Repeat dose every 4 hours if needed 1 teaspoonful DO NOT dren under 4 years of age

Inactive ingredients citric acid, FD&C blue no. 1, FD&C red no. 40, plycerin, grape flavor, purified water, sancharin sodium, sodium benzoate, sodium citrate, sorbitol solution. Other information store at room temperature

citric acid, FD&C blue no. 1, FD&C red no.

Other information store at room temper

glycerin, grape flavor, purified water,

citrate

ENDINOS

Inactive ingredients

Questions © 888-974-5279

Spring Valley, NY 10977 USA

West Stroot

Control # & Exp. Date

Silarx Pharmaceuticals, Inc.

Manufactured by:

Manufactured by: 19 West Street

Rev. 07/12

Questions © 888-974-5276

54838-104

Pharmaceuticals,

Spring Valley, NY 10977 USA Control # & Exp. Date

NDC 54838-104-70

Children's

Silfedrine Liquid

Pseudoephedrine Hydrochloride

Nasal Decongestant

- Non-drowsy Formula
- GRAPE FLAVOR
- Alcohol/Sugar Free

DO NOT USE IN CHILDREN **UNDER 4 YEARS OF AGE**

DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING

237 mL (8 fl oz)

354838-104-707

CHILDRENS SILFEDRINE

pseudoephedrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:54838-104
Route of Administration	ORAL	DEA Schedule	

	Active Ingredient/Active Moiety		
Ingredient Name		Basis of Strength	Strength
	Pseudoephedrine hydrochloride (Pseudoephedrine)	Pseudoephedrine hydrochloride	15 mg in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
anhydrous citric acid			
FD&C blue no. 1			
FD&C red no. 40			
glycerin			
saccharin sodium dihydrate			
sodium benzoate			
sodium citrate			
sorbitol			
water			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE (Grape Flavor)	Imprint Code	
Contains			

]	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:54838-104-40	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:54838-104-70	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 1/0 5/20 0 1	

Revised: 6/2014 Silarx Pharmaceuticals, Inc